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1 IN THE UNITED STATES DISTRICT COURT
 2 IN AND FOR THE DISTRICT OF DELAWARE

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4 NOVARTIS AG, NOVARTIS PHARMACEUTICALS : CIVIL ACTION
 CORPORATION, MITSUBISHI TANABE PHARMA :
 5 CORPORATION, and MITSUI SUGAR CO., LTD., :
 6 Plaintiffs, :
 v :
 7 ACTAVIS, INC. and ACTAVIS ELIZABETH, LLC, :
 8 Defendants. : NO. 14-1487-LPS

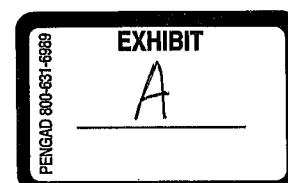
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 10 NOVARTIS AG, NOVARTIS PHARMACEUTICALS : CIVIL ACTION
 CORPORATION, MITSUBISHI TANABE PHARMA :
 11 CORPORATION, and MITSUI SUGAR CO., LTD., :
 12 Plaintiffs, :
 v :
 13 EZRA VENTURES, LLC, :
 14 Defendant. : NO. 15-150-LPS

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 16 NOVARTIS AG, NOVARTIS PHARMACEUTICALS : CIVIL ACTION
 CORPORATION, MITSUBISHI TANABE PHARMA :
 17 CORPORATION, and MITSUI SUGAR CO., LTD., :
 Plaintiffs, :
 v :
 18 HEC PHARM CO., LTD., HEC PHARM GROUP, :
 19 and HEC PHARM USA INC., :
 20 Defendant. : NO. 15-151-LPS

21 - - -
 22 Wilmington, Delaware
 23 Monday, June 22, 2015
 Telephone Conference

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 25 BEFORE: HONORABLE LEONARD P. STARK, Chief Judge

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1 APPEARANCES:

2 McCARTER & ENGLISH, LLP
 3 BY: DANIEL M. SILVER, ESQ.
 4 and
 5 WILMER CUTLER PICKERING HALE and DORR, LLP
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 8 (New York, New York)
 9 and
 10 WILMER CUTLER PICKERING HALE and DORR, LLP
 11 BY: KEVIN S. PRUSSIA, ESQ., and
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 13 (Boston, Massachusetts)
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 15 Novartis Pharmaceuticals Corporation
 16 STAMOULIS & WEINBLATT, LLP
 17 BY: STAMATIOS STAMOULIS, ESQ.
 18 and
 19 AMIN TALATI & UPADHYE, LLP
 20 BY: JOSEPH E. CWIK, ESQ.
 21 (Chicago, Illinois)
 22 Counsel for Ezra Ventures, LLC
 23 and
 24 FARNEY DANIELS, P.C.
 25 BY: MICHAEL A. SIEM, ESQ.
 (Brooklyn, New York)
 and
 FARNEY DANIELS, P.C.
 BY: JACQUELINE LU, ESQ.
 (Georgetown, Texas)
 Counsel for HEC Pharm Co., Ltd.,
 HEC Pharm Group, and HEC Pharm USA Inc.

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09:03:14 1 the plaintiff and one of them versus Ezra Ventures, LLC,
 09:03:19 2 which is Civil Action No. 15-150-LPS, and the other with HEC
 09:03:55 3 Pharm Group, et al., which is Civil Action No. 15-151-LPS.
 09:04:02 4 I set this call after receiving the letter from
 09:04:05 5 Mr. Stamoulis asking at least in part for clarification as
 09:04:11 6 to whether the order denying without prejudice to renew the
 09:04:16 7 motion to dismiss for lack of personal jurisdiction also
 09:04:24 8 apply to the alternative request for transfer in at least
 09:04:28 9 one of the cases, and I did want to make clear that the
 09:04:30 10 order intend to deny the motion for request of a transfer as
 09:04:36 11 an alternative remedy.
 09:04:39 12 But I thought we could certainly talk about that
 09:04:43 13 further, and also I believe the motion for certification of
 09:04:49 14 an interrogatory appeal which is opposed by plaintiffs I
 09:04:52 15 think is now fully briefed, and I thought that provided a
 09:04:56 16 good opportunity to talk as well about the case.
 09:04:58 17 I know there is also a pending request for
 09:05:01 18 scheduling including in the third case the Actavis case, and
 09:05:07 19 I don't believe those folks are on the phone this morning.
 09:05:10 20 So I don't want to get into any details about scheduling,
 09:05:14 21 but I did think in the context of these two cases, it might
 09:05:18 22 be helpful to talk about whether I should certify the
 09:05:21 23 interrogatory appeal and just sort of broadly whether and
 09:05:27 24 how these cases should go forward.
 09:05:28 25 So with that background, let me turn first I

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 2 P R O C E E D I N G S
 3 (REPORTER'S NOTE: The following telephone
 09:02:58 4 conference was held in open court, beginning at 9:02 a.m.)
 09:02:59 5 THE COURT: Good morning, everybody. This is
 09:02:49 6 Judge Stark. Who is there, please?
 09:02:51 7 MR. STAMOULIS: Good morning, Your Honor.
 09:02:52 8 MR. SILVER: Good morning, Your Honor.
 09:02:54 9 MR. STAMOULIS: I guess plaintiffs go first.
 09:02:56 10 I'm so used to being plaintiff. This is Stamatios
 09:03:00 11 Stamoulis, but I'm here with Dan Silver this time.
 09:03:02 12 MR. SILVER: Thank you, Mr. Stamoulis.
 09:03:03 13 Good morning, Your Honor. This is Dan Silver
 09:03:04 14 from McCarter & English on behalf of the plaintiffs. With
 09:03:07 15 me on the line from the law firm of WilmerHale are Jane
 09:03:12 16 Love, Robert Trenchard, Kevin Prussia, and Caitlin Looby,
 09:03:14 17 all who are admitted pro hac vice in these two actions.
 09:03:18 18 THE COURT: Thank you.
 09:03:19 19 MR. STAMOULIS: Good morning, Your Honor. This
 09:03:20 20 is Stamatios Stamoulis. And I'm Delaware counsel for both
 09:03:25 21 HEC and Ezra. With me on the line for HEC are Mike Siem and
 09:03:30 22 Jackie Lu. And with me on the line for Ezra is Joe Cwik.
 09:03:32 23 THE COURT: Good morning to all of you. And I
 09:03:37 24 have my court reporter here with me. And for the record,
 09:03:40 25 we're here in two matters, both with Novartis AG, et al as

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09:05:33 1 guess to defendants actually in whatever order the
 09:05:37 2 defendants wish.
 09:05:41 3 MR. CWIK: Yes, Your Honor. This is Joe Cwik
 09:05:44 4 for Ezra.
 09:05:47 5 You're correct, we have fully briefed the motion
 09:05:50 6 for certification for interrogatory appeal. In our opinion,
 09:05:54 7 this is a very close question of jurisdiction. We, of
 09:05:59 8 course, received your order denying our motion to dismiss,
 09:06:03 9 and we'll respect that order, but at the same time we think
 09:06:06 10 it is a very close question that could really use a Federal
 09:06:12 11 Circuit look at.
 09:06:14 12 You know, we've got to remember that I know
 09:06:16 13 that the Acorda and the AstraZeneca decisions were certified
 09:06:21 14 for appeal. I think Your Honor certified the Acorda case.
 09:06:25 15 In both those cases, the defendant was Mylan which is one of
 09:06:30 16 the largest generic companies in the world, so, of course,
 09:06:34 17 they have quite a few more contacts with Delaware than our
 09:06:38 18 client Ezra. Ezra, for all intents and purposes, is a small
 09:06:42 19 startup company in Arkansas.
 09:06:46 20 So on the continuum of facts, we have Mylan
 09:06:49 21 which has significantly more contacts in Delaware than our
 09:06:53 22 case. Our client is Ezra Pharmaceuticals in Arkansas. So
 09:06:58 23 that if the Acorda and the AstraZeneca fact patterns are a
 09:07:02 24 close enough question for Federal Circuit review, then
 09:07:04 25 certainly our set of facts which have much less contacts in

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1 Delaware should be even a closer question of jurisdiction
2 and would also benefit from a Federal Circuit review. That
3 is our position on the motion for interrogatory appeal as to
4 Ezra.

5 THE COURT: As to Ezra, is it your request,
6 what would you propose, with respect to whether I enter a
7 schedule and you go forward were I to certify the
8 interrogatory appeal on the jurisdiction issue?

9 MR. CWIK: Yes, Your Honor. If you were to
10 grant our motion, we would request a stay of the Delaware
11 case. That would be our preference.

12 The outlying facts and very unique facts
13 circumstance for Ezra is that we have the second suit in
14 Arkansas that was filed by plaintiffs. We didn't file that.
15 They filed that themselves. And in the Arkansas case, we
16 have a current trial date of April of 2016, just 20 months
17 from now -- ten months from now.

18 So it's our preference that we move forward in
19 the Arkansas case. We think it will be much more efficient
20 to move forward in the Arkansas matter. We will have a
21 trial in ten months from now. And most of the discovery, it
22 can be transferred to Delaware, if we ever do come back to
23 Delaware someday. And we're certainly willing to meet and
24 confer with opposing counsel to figure out how that would be
25 done, and if there was any objections to transferring that

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1 discovery.

2 But we have this unique circumstance where we
3 have an Arkansas court ready to try this same patent, these
4 same set of facts ten months from now. Essentially, what
5 the Arkansas court is going to do is it is going to go
6 through the jungle with a machete first, it's going to clear
7 a path, it's going to issue its *Markman* opinion, it's going
8 to weigh the evidence, it's going to listen to the witnesses
9 and ultimately issue an opinion at a trial in Arkansas and
10 essentially do a lot of the work that this Court would
11 ultimately have to do anyway. Of course, Your Honor is not
12 bound by what the Arkansas case does, but it certainly would
13 clear the way and make things easier to the Delaware Court
14 in our opinion.

15 THE COURT: So Mr. Cwik, what is the status of
16 the Arkansas case right now? Do you have a *Markman* hearing
17 coming up?

18 MR. CWIK: Your Honor, the status of the case is
19 the Judge has entered a preliminary scheduling order that
20 will set us for trial in April of 2016, ten months from
21 know. The Rule 26(f) reports are due today. We have
22 tendered a report to the opposing side that built in a
23 *Markman* schedule. I think our briefing of the *Markman*
24 scheduling is done by September 1st of this year is what
25 our proposal is. They have not given us a counterproposal

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1 because they have moved to stay the Arkansas case. The last
2 brief on that motion to stay was filed last Friday.

3 We understand that the Arkansas case moves
4 fairly quickly on substantive issues but procedural issues
5 like motions to stay sometimes can take quite a while, so we
6 don't anticipate a ruling right away on the motion, but that
7 is the status of the Arkansas case.

8 THE COURT: All right. Well, thank you for
9 that. We'll come back to you.

10 But is there anything that HEC defendants want
11 to add?

12 MR. SIEM: Your Honor, this is Michael Siem from
13 Farney Daniels.

14 We agree with defendant Ezra. Our case is very
15 similar in that we have no contacts with Delaware. We sent
16 the notice letter into New Jersey, and we are again kind of
17 a newer company in that we don't sell any products into the
18 U.S.

19 So we think we're significantly different than
20 what we saw in the Delaware with the Mylan defendants in
21 those cases. And we believe that, we would request that we
22 get the interrogatory appeal to get that ruled on and then
23 stay the Delaware case also.

24 THE COURT: All right. Thank you.
25 Well, then let me hear from plaintiffs, please.

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1 MR. PRUSSIA: Thank you, Your Honor. This is
2 Kevin Prussia from WilmerHale. If I could, I'll address the
3 Arkansas question just to clarify exactly what is going on
4 in that venue.

5 As Your Honor knows, we filed a protective suit
6 in Arkansas in the chance that the Ezra defendant would
7 contest jurisdiction in Delaware, which it did. It is
8 certainly true that that Court has set a date for April
9 2016. That was pursuant to what I understand is a form
10 scheduling order that it issued in cases as they're filed.
11 There was no date in there for *Markman*. There were no dates
12 in there for contentions or any of the other sorts of things
13 that are unique to patent cases.

14 And as we understand it from our local counsel,
15 the date is not going to stick. The average trial time in
16 Arkansas for patent cases is 30 months. So the idea that
17 this case is going to get tried in April 2016 in Arkansas, I
18 have to say I think it is not one that reflects reality and
19 certainly not one that is consistent with the history of
20 that jurisdiction.

21 There has been nothing that has occurred in
22 Arkansas to give us the sense that somehow now it has become
23 this "rocket docket." There hasn't even been a scheduling
24 order that has been -- discovery plan that has been entered
25 yet in the case. It is due today. There are no schedule

<p style="text-align: center;">10</p> <p>1 for contentions, as I mentioned. There is no date for 2 <i>Markman</i>. None of that is on the calendar. 3 Just to take a step back as to the landscape of 4 what is going on with these products and these patents. 5 There are three patents covering this product, Gilenya, 6 which was approved in 2010, and it is the first oral drug 7 that was approved by the FDA to treat multiple sclerosis. 8 There are three patents. There are two at issue in this 9 case. One is a compound patent that expires in February of 10 2019. The other is a formulation patent which is in the 11 case pursuant to a counterclaim by HEC, and that expires 12 March of 2026. There is another patent that hasn't been 13 challenged by any party. That doesn't expire until 14 September of 2017. 15 So regardless of when all these cases resolve 16 themselves, there will be no FDA approval for any generic 17 drug for Gilenya because every generic that has submitted an 18 application has submitted a paragraph III on that patent 19 that expires in September of 2017. 20 So we proposed a trial date in Delaware that all 21 the generics, all three generics, Actavis, Ezra, and HEC, 22 had agreed to, which is five months before that September 23 2017 expiration date for that patent that is not challenged 24 by any defendant. 25 So we're not in a situation here where there is</p>	<p style="text-align: center;">12</p> <p>1 facts. They say, hey, we've got different facts here. 2 Our facts are different from AstraZeneca. Our facts are 3 different from Acorda. 4 Well, that really isn't enough. 1292(b) isn't 5 supposed to be about facts, it's supposed to be controlling 6 questions of law. They essentially admitted this is a 7 dispute over facts, and we think that is insufficient to 8 present a controlling question of law. 9 So it's not an exceptional case. It doesn't 10 present the controlling question of law. 11 So the next question is, is there a substantial 12 ground for difference of opinion? And we think no. 13 Now, they disagree with the rulings, but the fact 14 of the matter is Your Honor wasn't allowed -- every single 15 motion that has been filed by every single generic, all of 16 which are copycat motions to dismiss for jurisdictional 17 grounds has been dismissed -- has been denied all across the 18 country, not just in Delaware but in New Jersey, in Texas, in 19 Indiana, in Illinois, all across the country. 20 Now, I guess everyone could be wrong, and I 21 guess the Federal Circuit will let us know some time this 22 year or at the beginning of next year, but there is no 23 substantial difference of opinion. There has been harmony, 24 unanimity in the way this issue has been decided across the 25 country. So I don't think that favors granting a petition</p>
<p style="text-align: center;">11</p> <p>1 pending generic entry. We have NCE exclusivity that doesn't 2 even expire until September of this year. We've got a 30 3 month statutory stay that adds on to that. And we've got a 4 patent that doesn't expire until September of 2017, that no 5 one has challenged. 6 On the certification question, Your Honor, I 7 just want to raise a few points. 8 The first is that, as Your Honor knows, 9 certification is supposed to be granted sparingly and only 10 in exceptional cases, and the AstraZeneca and the Acorda 11 case is already up to the Federal Circuit presenting this 12 issue of jurisdiction in Hatch-Waxman cases. 13 The scope of the question that is to be 14 addressed by the Federal Circuit was not limited to the 15 narrow question as to whether mailing a paragraph IV notice 16 letter to a Delaware citizen is sufficient to trigger 17 specific jurisdiction. It was a much broader question. 18 And the Federal Circuit, that briefing has 19 already started. The opening merits brief was filed I think 20 a month or so ago. Responsive merits brief I think is due 21 next month. It is well ahead. 22 And there is nothing particularly exceptional 23 about this case that would warrant the 1292(b) petition to 24 be granted. As my colleagues just mentioned, essentially 25 they just disagree with Your Honor's ruling based on the</p>	<p style="text-align: center;">13</p> <p>1 either. 2 The third question is whether an immediate 3 appeal will have some material impact on this case that 4 would ultimately advance the litigation. I think there 5 again the answer is no; and that is for a few reasons. 6 The first is, as I said, there is a patent that 7 is not challenged that is in place that does not expire 8 until September of 2017. There no imminence here with 9 respect to the resolution of this case on the merits. That 10 is one. 11 The second reason is, and it is always hard to 12 predict what the Federal Circuit is going to do, but it 13 seems to me highly unlikely they're going to take up this 14 appeal having just granted a petition in the Acorda and 15 AstraZeneca cases. I think we all on this phone know the 16 Federal Circuit rarely takes up these interrogatory appeals. 17 It did so on a broad legal issue, and the idea it is going 18 to take up additional cases just doesn't seem to be likely. 19 And you don't need to take my word for it. You 20 can just look across the country and see what has happened 21 in all these other cases in which motions to dismiss were 22 denied. There have been no other cases for which a 1292(b) 23 motion was granted. And, of course, there are no -- it 24 follows there are no other cases that are pending before the 25 Federal Circuit aside from AZ and Acorda. I think that is a</p>

<p style="text-align: center;">14</p> <p>1 strong indication that the likelihood of this being accepted 2 on appeal is pretty low.</p> <p>3 So, Your Honor, in short, there is a case that 4 is pending in this jurisdiction against Actavis. It is 5 going to go forward. They don't contest jurisdiction. 6 We've got HEC and Ezra. They disagree with Your Honor's 7 ruling. That is their right. They can take that up in the 8 normal course in the appeal of this case once we have final 9 judgment. But there is a case that is going to proceed in 10 Delaware.</p> <p>11 Therefore, for judicial economy, for party 12 efficiency, there are a whole host of reasons why these 13 cases should all proceed together, in harmony. There is no 14 need for parallel litigation. These are all first filed 15 cases. There is a strong presumption in proceeding with 16 first filed cases in the forum that plaintiff chooses. And 17 there really is nothing exceptional as presented by these 18 particular circumstances that would justify from departing 19 that well established rule here.</p> <p>20 THE COURT: All right. Mr. Prussia, what about 21 certifying and not staying this case? Why shouldn't I 22 contemplate that?</p> <p>23 MR. PRUSSIA: Well, Your Honor, I just don't 24 think this meets the criteria for granting a 1292(b) motion. 25 You know, the most important thing for us is proceeding with</p>	<p style="text-align: center;">16</p> <p>1 decisions that have denied personal jurisdiction motions 2 similar to Ezra's across the country, we all know that 3 Mylan has been filing the motion to dismiss for personal 4 jurisdiction on almost every case that they do, so I think 5 80 or 90 percent of the denials of personal jurisdiction 6 motions have been Mylan's motions, so all dealing with the 7 Mylan set of facts.</p> <p>8 Again, our set of facts is very different than 9 the Mylan set of facts. We're a small startup company in 10 Arkansas. Mylan is one of the largest generic pharma 11 companies in the world. So we think the Court would really, 12 the Federal Circuit would benefit from our fact pattern in 13 distinguishing really what is the line where enough contacts 14 are enough contacts for a pharma company to be in Delaware.</p> <p>15 Thank you, Your Honor.</p> <p>16 THE COURT: Well, help me on this, Mr. Cwik. 17 Given the status of the two appeals that have already been 18 certified and are well underway in briefing, isn't it 19 possible, maybe even likely, if I were to certify this one, 20 you will be significantly behind the others, and before 21 your appeal can be resolved, there will be a decision in 22 the others and then perhaps even at that point, the Federal 23 Circuit might send your case back to me so that I can, in 24 the first instance, evaluate the application of whatever 25 they say in the other cases to this one.</p>
<p style="text-align: center;">15</p> <p>1 discovery. So if Your Honor feels inclined to grant the 2 1292(b) motion and proceeding with discovery in that forum, 3 that is something that, while it wouldn't be our first 4 choice, it is something we would be fine with. But we don't 5 think that this meets the standard for a granting a 1292(b) 6 petition.</p> <p>7 And we don't think the Federal Circuit is likely 8 to take it. It hasn't happened in any other case. We just 9 think it is going to increase litigation costs to have to 10 brief this issue again to the Federal Circuit, given the low 11 likelihood that it is going to take it.</p> <p>12 THE COURT: All right. Thank you. Let me turn 13 back in guess first to Ezra. Mr. Cwik, is there anything 14 you want to add?</p> <p>15 MR. CWIK: Your Honor, a couple things.</p> <p>16 On the Arkansas case, yes, it's true that the 17 Arkansas case could theoretically change, but we received 18 no indication whatsoever that it will actually change. The 19 presumption is that as the schedule will stay in place. We 20 have built in a schedule and proposed something so that the 21 <i>Markman</i> issue can be resolved in time.</p> <p>22 You know, Ezra is different. Ezra does not have 23 a counterclaim on the formulation patent that HEC does, so 24 we're a little bit different on that point.</p> <p>25 And as far as the other personal jurisdiction</p>	<p style="text-align: center;">17</p> <p>1 That is part of one of my concerns in your case. 2 And another way to put it I guess is if I were to consider 3 taking the unusual move of certifying interrogatory appeal, 4 why wouldn't it be better to consider doing that after we 5 hear from the Federal Circuit in the other cases as quickly 6 as possible, apply that ruling to your facts here and then, 7 if you are unhappy with the result, we certify for an 8 interrogatory appeal? I can't envision doing it twice is 9 part of what I'm thinking. So all these things are concerns 10 I have as I decide whether or not to certify right now the 11 interrogatory appeal you're proposing.</p> <p>12 Comment on any of that, if you would, please.</p> <p>13 MR. CWIK: Yes. Thank you, Your Honor.</p> <p>14 You are correct that is a possible scenario.</p> <p>15 But if we look at the Mylan appeals that are going on and 16 the Mylan contacts with Delaware, there is a variety of 17 facts that the Federal Circuit could affirm on that simply 18 aren't present for Ezra.</p> <p>19 We know that Mylan is registered to do business 20 in Delaware. That could be a reason for the Federal Circuit 21 to affirm that wouldn't apply to us.</p> <p>22 We know that Mylan has sued in Delaware, been 23 sued in Delaware multiple times. Those contacts could be a 24 reason for the Federal Circuit to affirm those opinions that 25 don't apply in our case.</p>

<p style="text-align: center;">18</p> <p>1 We know that Mylan has sold products and 2 continues to sell products into Delaware. Those are 3 also facts where the Federal Circuit could affirm the 4 jurisdiction in Delaware, and those contacts aren't 5 present for Ezra.</p> <p>6 So, sure, we could learn something from the 7 Federal Circuit opinion, but I think it is just as likely 8 that the AstraZeneca and the Acorda opinions really won't 9 resolve the jurisdiction question as it applies to a smaller 10 limited pharma company that Ezra is and I presume HEC is. I 11 can't speak for HEC, but I understand they're in a similar 12 circumstance,</p> <p>13 MR. PRUSSIA: Your Honor, if I could just 14 interject just to sure make we clear the points on that.</p> <p>15 THE COURT: Yes. Hold on a second.</p> <p>16 Mr. Cwik, is there anything else you wanted to 17 add?</p> <p>18 MR. CWIK: That's it, Your Honor. Thank you.</p> <p>19 THE COURT: And then for HEC, Mr. Siem, is there 20 anything you want to add?</p> <p>21 MR. SIEM: Yes, Your Honor.</p> <p>22 The plaintiffs continually say this is an issue 23 of fact. There is no argument about the facts in this, and 24 what contacts we actually have with Delaware. What it is an 25 application of the broad standard of law that this Court has</p>	<p style="text-align: center;">20</p> <p>1 Mr. Prussia, you may add something if you wish.</p> <p>2 MR. PRUSSIA: Thank you, Your Honor. And I'll 3 be brief.</p> <p>4 The first is I think Your Honor is exactly 5 right. Whatever the Federal Circuit decides is going to 6 have some bearing on this case; and there is going to need 7 to be some application of that based on how the Federal 8 Circuit rules. And Your Honor denied this motion without 9 prejudice with leave to renew for that reason.</p> <p>10 So it is not clear to me what exactly would be 11 certified, because there really isn't a decision here.</p> <p>12 There is no real opinion here to certify because Your Honor 13 denied the motion without prejudice contemplating that how 14 the Federal Circuit rules in AstraZeneca or Acorda may have 15 some bearing on this issue in this case. So I don't really 16 even think procedurally at this point there is anything to 17 even actually certify.</p> <p>18 The second point, Your Honor, is that we're kind 19 of here in this -- what is a little frustrating about this 20 issue is we're sort of operating here under a fiction.</p> <p>21 Defendants have not denied when their product 22 is approved, they're going to sell product in Delaware. And 23 there is no dispute that if this were anything but the 24 artificial world of infringement under 271(e), there would 25 be jurisdiction here. Congress passed a statute so that we</p>
<p style="text-align: center;">19</p> <p>1 applied. So we think what they're doing in the Federal 2 Circuit is a much broader question of jurisdiction that, as 3 Mr. Cwik said, could potentially not resolve our case. And 4 that even if they did send it down, they may not give us 5 sufficient guidance.</p> <p>6 I also want to point out Mr. Prussia points out 7 there is no other case and no other courts that have applied 8 the law in the way that we asked for them to. That is just 9 not true. We have had other cases in New Jersey where the 10 Court has declined to assert jurisdiction. So there -- 11 well, most of the courts have gone with Mylan, where they 12 have 90 percent of the cases are that way, and that Mylan is 13 a large company that sells products all over the country. 14 We have a very substantially different case and cases that 15 are close to us, the Court has declined to assert jurisdiction.</p> <p>16 So in reading the briefing and looking at what 17 we have, it is a factually different situation, a much 18 more narrower question than what is up on appeal for the 19 AstraZeneca cases and the Acorda cases.</p> <p>20 So what we would like and what we think is that 21 the Court should get some guidance on the facts we have 22 here where there are no contacts in Delaware at all, not 23 even serving a notice letter to Delaware. So we agree with 24 Mr. Cwik and Ezra on this.</p> <p>25 THE COURT: All right. Thank you.</p>	<p style="text-align: center;">21</p> <p>1 wouldn't have to wait for that harm to happen. We wouldn't 2 have to wait until the market was destroyed by generic entry 3 to sue. There was nothing in the Hatch-Waxman statute that 4 suggested that somehow when it did that, the jurisdiction 5 analysis was going to be curtailed. That somehow patent 6 owners in Hatch-Waxman cases have secondary rights to patent 7 owners in cases which there are products launched on the 8 market.</p> <p>9 So all the stuff about we have less contacts 10 than Mylan, Mylan is a big generic company, that is a big 11 fiction. They are going to be selling product into the 12 market. They haven't denied that at any point in the 13 briefing.</p> <p>14 The last point I'll offer, Your Honor, is that 15 we think that the reason why 1292(b) is reserved for sparing 16 exceptional cases is to protect against situations like 17 this where we now have generics that in every Hatch-Waxman 18 case, it is almost an automatic thing. They file a motion 19 to dismiss for lack of personal jurisdiction on the same 20 grounds that have been asserted by Mylan and the other 21 generic defendants. And what it is doing to these cases, 22 as I'm sure Your Honor has seen on your docket, is it has 23 cluttered the docket with these copycat motions and it has 24 provided greater uncertainty in these cases as to what is 25 going to happen.</p>

<p style="text-align: center;">22</p> <p>1 We spent now months fighting over whether the</p> <p>2 first filed case is going to be stayed, whether the second</p> <p>3 filed case is going to be stayed, whether it should be</p> <p>4 transferred, whether it should be a 1292(b) instead of</p> <p>5 proceeding on the merits of the case as we should be doing</p> <p>6 with a 30 month stay.</p> <p>7 Respectfully, I think that granting a 1292(b)</p> <p>8 petition in this case would only further incentivize that</p> <p>9 litigation strategy by the generics, and we respectfully</p> <p>10 request you do not do so.</p> <p>11 THE COURT: All right. Thank you. Is there</p> <p>12 anything further, Mr. Cwik?</p> <p>13 MR. CWIK: No, Your Honor. Thank you.</p> <p>14 THE COURT: And Mr. Siem?</p> <p>15 MR. SIEM: Your Honor, one point. The Court has</p> <p>16 to be looking at the context that we have, that HEC has at</p> <p>17 the time it was filed, not what we're going to be doing in</p> <p>18 the future and potentially going into Delaware which has not</p> <p>19 been determined yet.</p> <p>20 So when we look at this and look at the cases,</p> <p>21 the Court, as it has indicated, has to look at the time at</p> <p>22 when the case was filed as to our jurisdictional contacts.</p> <p>23 And so that question is something we will not get an answer</p> <p>24 from the Acorda case, and that is why it is a much broader</p> <p>25 question than what we have here. And we're looking, we</p>	<p style="text-align: center;">24</p> <p>1 about my discretion more broadly, I have decided that these</p> <p>2 are not cases in which I should go ahead and certify.</p> <p>3 The first factor is whether there is a</p> <p>4 controlling question of law.</p> <p>5 On this one, I do think the defendants have</p> <p>6 met their burden. I think the question here is whether or</p> <p>7 not there is personal jurisdiction in Delaware over the</p> <p>8 defendants in these Hatch-Waxman cases. And while I think</p> <p>9 that there is, under the current law, that is not the</p> <p>10 issue really for today. The issue is whether that is a</p> <p>11 controlling question of law, and I think it is. Because</p> <p>12 if I'm wrong, then this Court lacks jurisdiction and this</p> <p>13 case will have to end. So in my view, that is a controlling</p> <p>14 question of law.</p> <p>15 Next is whether there is substantial grounds</p> <p>16 for difference of opinion.</p> <p>17 Here, again, I think the defendants have actually</p> <p>18 met their burden, notwithstanding if the plaintiffs are</p> <p>19 correct that the scorecard currently is that these motions</p> <p>20 are being denied uniformly. As I found in the context of</p> <p>21 the Acorda case, I believe that there is substantial ground</p> <p>22 for difference of opinion. None of us know what the Federal</p> <p>23 Circuit's view is going to be of this. I think different</p> <p>24 questions are presented in which reasonable minds can.</p> <p>25 Differ. So I do think that there are substantial grounds</p>
<p style="text-align: center;">23</p> <p>1 think we can use some guidance from the Federal Circuit.</p> <p>2 THE COURT: All right. But, Mr. Siem, you don't</p> <p>3 deny that if HEC gets approval to market its drug product,</p> <p>4 that it will end up in Delaware; correct?</p> <p>5 MR. SIEM: Your Honor, actually we don't know</p> <p>6 who will be distributing the product because it will not</p> <p>7 be distributed by HEC. It will be distributed by another</p> <p>8 partner.</p> <p>9 THE COURT: Right. But can you make any</p> <p>10 representation now that whoever distributes or markets it is</p> <p>11 going to carve out of the market the State of Delaware?</p> <p>12 MR. SIEM: No, we can't, Your Honor.</p> <p>13 THE COURT: Thank you. Well, this has been very</p> <p>14 helpful. Let me say a few things.</p> <p>15 Having given it a lot of thought and had some</p> <p>16 questions answered today, I am going to go ahead and deny</p> <p>17 the 1292(b) motion that is the request from the two sets</p> <p>18 of defendants on the call today for certification of an</p> <p>19 interrogatory appeal.</p> <p>20 As I think everyone agrees, the law directs that</p> <p>21 I grant such a motion sparingly and sets out three factors</p> <p>22 that I should consider in deciding whether to exercise my</p> <p>23 discretion to treat these cases as among those rare</p> <p>24 instances where I would certify.</p> <p>25 Having applied those three factors and thought</p>	<p style="text-align: center;">25</p> <p>1 for difference of opinion.</p> <p>2 However, it is when I come to the third factor</p> <p>3 that I find defendant have not proven to my satisfaction that</p> <p>4 certification in these cases in the particular circumstances</p> <p>5 here would materially advance termination of these cases.</p> <p>6 And, further, I think the appropriate exercise of my</p> <p>7 discretion under the overall circumstances is not to interrupt</p> <p>8 these cases with an interrogatory appeal.</p> <p>9 First, were I to certify, I would be confronted</p> <p>10 with the question of whether to grant the request of the</p> <p>11 defendants for a stay of litigation here while the battle is</p> <p>12 taken up in the Federal Circuit.</p> <p>13 And I think it probably would not be wise for</p> <p>14 me to stay these two cases for reasons including that the</p> <p>15 third Actavis case is going forward. For the further reason</p> <p>16 that the jurisdictional dispute is not one that is going to</p> <p>17 ultimately eliminate the litigation between the plaintiffs</p> <p>18 and the two sets of defendants on the call today. It's</p> <p>19 only -- and I don't mean to minimize it but it's only a</p> <p>20 battle or where that litigation is going to take place. So</p> <p>21 staying these cases and just putting them on hold I don't</p> <p>22 think accomplishes much and at a minimum does not materially</p> <p>23 advance termination of the litigation because, again, the</p> <p>24 cases have to go forward somewhere at some point as long as</p> <p>25 the defendants continue to desire to market, to be approved</p>

26

1 and ultimately market their generic drug.

2 I am also concerned, as I raised during the
3 discussion, about piecemeal litigation which generally we
4 try to avoid, but here the piecemeal litigation it seems
5 to me could really be multiplied were I to certify an
6 Interrogatory appeal now, and whether or not I stayed these
7 cases pending the Interrogatory appeal, there is at least a
8 reasonable chance I believe that the Federal Circuit will
9 rule in the Acorda, AstraZeneca cases before the current
10 case in front of me that we're talking about now is
11 concluded, and then somebody, either the Federal Circuit or
12 me, would have to apply what the law is after the Federal
13 Circuit rules to the specific circumstances and facts
14 presented here, all of which I think could lead to a request
15 for certification of an Interrogatory appeal from that
16 subsequent decision were I to be the one to make it.

17 Here is where my discretion comes in as well.
18 I do think that certainly in the overwhelming majority of
19 matters, the Court of Appeals wants a District Judge to be
20 making these decisions in the first instance. And that is
21 what in part motivated my decision to deny without prejudice
22 the motion to dismiss and to transfer in the first instance
23 without prejudice to renew thinking that it's probably
24 best that the parties be given a chance and hopefully a
25 very expeditious manner to give me briefing, should the

27

1 defendants wish to renew their motion, to give me briefing
2 telling me how to apply whatever it is the Federal Circuit
3 says in the Acorda and AstraZeneca cases to the facts and
4 circumstances here. We'll take that motion up as quickly as
5 we possibly can, if it is renewed. And if anyone is unhappy
6 with the result, then you can seek a certification of an
7 Interrogatory appeal at that time, and we'll evaluate that
8 request in the context in which it arises.

9 The further factors that I have considered that
10 I think favor exercising my discretion to make the decision
11 I'm making today include the fact that there are the
12 multiple patents here, and no matter what I do, no matter
13 which Court is handling these cases, be it a District Court
14 or the Federal Circuit, be it this District or the District
15 of Arkansas, I'm advised there are no circumstances in which
16 the defendants could be marketing their generic products
17 until more than two years from now, in September of 2017
18 based on their paragraph III filings.

19 So all of that suggests to me, again, that
20 the proper exercise of my discretion, given the defendants'
21 failure on the third factor for a 1292(b) motion, given that
22 those motions are granted sparingly, is, as I have said, to
23 deny the certification request and then turn my attention,
24 as I will in due course, to what is the appropriate schedule
25 in these matters so that the cases can go forward.

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1 Let me further add that, I'll get an oral order
2 out to this effect, but I do want the parties to provide a
3 joint status report within seven days of whenever the
4 Federal Circuit issues a decision in one or both of the
5 pending Acorda, AstraZeneca Interrogatory appeals. And in
6 that status report, I would expect to see what the parties
7 proposals are for whether or not the motion to dismiss is
8 going to be renewed, and, if so, how quickly and how
9 succinctly such a motion can be briefed, so, again, we can
10 resolve that as expeditiously as possible and allow you all
11 to consider your options at that point.

12 So I don't want to have any reargument, but I
13 have said a lot. I want to make sure that it has been
14 understood and see if you have any questions about any of
15 that.

16 First, Mr. Cwik?

17 MR. CWIK: Yes, Your Honor. Thank you for your
18 time on this matter. It is appreciated.

19 We understand your order. I guess one quick
20 question I had on the motion to renew or motion to dismiss
21 for the personal jurisdiction, would that be seven days of
22 the Federal Circuit decision or seven days of the Federal
23 Circuit mandate?

24 THE COURT: I would like to hear from you all
25 within seven days of the Federal Circuit decision. If, at

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1 that time, having seen the decision, anyone thinks that
2 perhaps the renewal of the motion should wait for the
3 mandate, that is something you can discuss in your status
4 report.

5 MR. CWIK: Okay.

6 THE COURT: Understood?

7 MR. CWIK: Yes, Your Honor. Thank you.

8 THE COURT: Okay. Mr. Siem?

9 MR. SIEM: Nothing further, Your Honor. Thank
10 you.

11 THE COURT: Okay. Mr. Prussia?

12 MR. PRUSSIA: Nothing further from plaintiffs,
13 Your Honor. Thank you.

14 THE COURT: Thank you all very much for your
15 time. Good-bye.

16 (Telephone conference ends at 9:43 a.m.)

17
18 I hereby certify the foregoing is a true and accurate
19 transcript from my stenographic notes in the proceeding.

20 /s/ Brian P. Gaffigan
21 Official Court Reporter
22 U.S. District Court
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